REMARKS/ARGUMENTS:

Claim 23 is canceled without prejudice. Claims 12-14 are withdrawn from consideration. Claim 15 is amended. New claims 25-35 are added. Claims 12-22 and 24-35 are pending in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

The present invention relates to a novel peptide having osteogenetic activity and an osteogenetic accelerator containing the same as an active ingredient. The peptide of the present invention, which has the osteogenetic activity, is useful for treatment of fractures, as a filler in deficient sites of bone, for inhibition of decrease in bone substance related to osteoporosis and periodontic diseases, for prevention of fractures associated with osteoporosis and rheumatoid arthritis and the like. (Applicant's specification, at p. 1, lines 11-20).

CLAIM OBJECTIONS:

Claims 12-14 stand objected to because they contain recitations of non-elected amino acid sequences. In response, the Applicant withdraws claims 12-14 from consideration.

However, the Applicant reserves the right to have SEQ ID NO:8 reconsidered if it is found that claims directed to SEQ ID NO:11 are patentable. SEQ ID NO:8 and SEQ ID NO:11 are not mutually exclusive, but rather SEQ ID NO:11 represents a species of the genus described by SEQ ID NO:8

> "Claims to be restricted to different species must be mutually exclusive. The general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while a second claim recites limitations disclosed only

for the second species and not the first. This is frequently expressed by saying that claims to be restricted to different species must recite the mutually exclusive characteristics of such species." MPEP 806.04(f)

CLAIM REJECTIONS UNDER 35 U.S.C. § 102:

Claims 12-17, 19, 22 and 24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Oppermann et al. (WO89/09788). This rejection is moot with respect to claims 12-14 due to the withdrawal of these claims. The Applicant respectfully traverses this rejection as to claims 15-17, 19, 22, and 24. Claim 15 was amended to include all the limitations of canceled claim 23. Claim 23 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Oppermann et al. (WO89/09788) in view of Lipton (U.S. Patent No. 5,028,592). Claim 15, as amended, is as follows:

> A synthesized peptide comprising the sequence SEQ ID NO:11, wherein the peptide N-terminal is acetylated, or the peptide C-terminal is amidated, or both the N-terminal is acetylated and the C-terminal is amidated.

Applicant respectfully submits that Oppermann and Lipton cannot render claim 15 obvious because Oppermann and Lipton fail to teach or suggest SEQ ID NO:11, wherein the peptide N-terminal is acetylated, or the peptide C-terminal is amidated, or both the N-terminal is acetylated and the C-terminal is amidated.

The Office acknowledges that Oppermann does not disclose a peptide being N-terminal acetylated or C-terminal amidated. However, the Office states that at the time the invention was made, it would have been obvious that one of ordinary skill in the art is motivated to use the peptide comprising SEQ ID NO:11 taught by Oppermann to prepare the protected peptide by amidation at C-terminal or acetylation at N-terminal as taught by Lipton because the peptide with N- or C-

terminal protection would be less susceptible to acid hydrolysis or enzymatic attack and degradation, and in addition, it would be more active pharmacologically than the unprotected peptide.

In response, the Applicant respectfully submits that there is no motivation or suggestion to combine the teaching of Oppermann with the teaching of Lipton in the manner suggested by the Office. Furthermore, if the teaching of Oppermann were to be combined with the teaching of Lipton, the principle of operation of Oppermann would be destroyed. Oppermann, as acknowledged by the Office, teaches a synthetic osteogenic protein comprising an amino acid sequence of OP1 (102 amino acids), which contains the amino acid sequence of SEQ ID NO:11 at residues 57-76. An acetylation at the N-terminal end (residue 57) of SEQ ID NO:11 or an amidation at the C-terminal end (residue 76) of SEQ ID NO:11 would shorten the OP1 102 amino acid sequence. Consequently, the synthetic osteogenic protein taught by Oppermann would no longer exist.

> "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." MPEP 2143.01

In light of the foregoing, Applicant respectfully submits that Oppermann and Lipton could not have made claim 15 obvious, because the combination of references fails to teach or suggest each and every claim limitation. Claims 16, 17, 19, 22, and 24 depend from claim 15 and therefore, cannot be rendered obvious over the cited references for at least the same reasons discussed above. Withdrawal of this rejection is thus respectfully requested.

Claims 12-22 and 24 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Rueger et al. (U.S. Patent No. 6,281,195). This rejection is moot with

respect to claims 12-14 due to the cancellation of these claims. The Applicant respectfully traverses this rejection as to claims 15-22 and 24. As discussed above, claim 15 was amended to include all the limitations of canceled claim 23. Claim 23 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Oppermann et al. (WO89/09788) in view of Lipton (U.S. Patent No. 5,028,592).

Claim 15 and its dependent claims 16-22 and 24 cannot be rendered obvious over Oppermann and Lipton for the same reasons discussed above. Rueger cannot remedy the defect of Oppermann and Lipton and is not relied upon by the Office for such. Instead, the Office cites Rueger for teaching a protein which comprises SEQ ID NO:11, as well as for teaching some of the possible carriers of the present invention, and for teaching the concentration of protein with respect to both carrier and solvent.

In light of the foregoing, Applicant respectfully submits that Rueger, Oppermann and Lipton could not have made claims 15-22 and 24 obvious, because the combination of references fails to teach or suggest each and every claim limitation. Withdrawal of this rejection is thus respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103:

Claims 12-17, 19, and 22-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Oppermann et al. (WO89/09788) in view of Lipton (U.S. Patent No. 5,028,592). This rejection is moot with respect to claims 12-14 and 23 due to the cancellation of these claims. The Applicant respectfully traverses this rejection as to claims 15-17, 19, 22, and 24 for the same reasons discussed above. Withdrawal of this rejection is thus respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California telephone number (213) 337-6700 to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted,
HOGAN & HARTSON L.L.P.

Date: January 31, 2005

By: Lawrence J. McClure
Lawrence J. McClure
Registration No. 44,228
Attorney for Applicant(s)

500 South Grand Avenue, Suite 1900
Los Angeles, California 90071
Phone: 213-337-6700
Fax: 213-337-6701